UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/817,507	04/17/97	KISHIMOTO T	53466/201

HM12/0228

HAROLD WEGNER
FOLEY & LARDNER
3000 K STREET NW SUITE 500
PO BOX 25696
WASHINGTON DC 20007-8696

EXAMINER	
CANELLA,K	
ART UNIT	**PAPER NUMBER**
1642	29

DATE MAILED: 02/28/01

Please find below and/or attached an Office communication concerning this application r proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/817,507	Kishimoto
Examiner	**Group Art Unit**
Karen Canella	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3 months* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *15 and 24-28* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☒ Claim(s) *25 and 28* is/are allowed.

☒ Claim(s) *15, 24, 26, and 27* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *23*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The request filed on 5/26/00, in Paper No. 24, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/862,442 is acceptable and a CPA has been established. An action on the CPA follows.

2. Claims 16-23 have been canceled. Claims 15, 25 and 28 have been amended. Claims 15, and 24-28 are under consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 15, 24, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 15, 24, 26 and 27 are drawn to a method of treating a human cachexia comprising the administration of an anti-Il-6 receptor antibody, wherein the antibody inhibits signal transduction by Il-6 and the binding of Il-6 to Il-6 receptor. The written description in this case only sets forth PM-1 and therefore the written description is not commensurate in scope with the claims drawn to generic antibodies which bind to the Il-6 receptor and interfere with Il-6 binding and signal transduction.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed. (See page 1117). The specification does not clearly allow persons of

ordinary skill in the art to recognize that the applicant invented what is claimed. (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). The specification teaches a method for treating cachexia comprising the administration of humanized PM-1 which blocks signal transduction by Il-6 and the binding of Il-6 to the Il-6 receptor. It is known in the art that the gp80 subunit of the Il-6 receptor functions to bind Il-6, and two different epitopes on gp80 have been identified with Il-6 binding (Liautard et al, Eur. Cytokine Netw, 1994, Vol. 5, pp. 293-300). Claims 15, 24, 26 and 27 are broadly drawn to encompass antibodies which bind at both epitopes. However, no disclosure, beyond PM-1 and the mere contemplation of additional antibodies which bind to the Il-6 receptor and thereby interfere with the binding of Il-6 is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only a method of treating human cachexia comprising the administration of the PM-1 antibody but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 15 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emilie et al (Blood, 1994, Vol. 84, pp. 2472-2479) in view of Sato et al (Cancer Research, 1993, Vol. 53, pp. 851-856). Claims 15 and 24-28 are drawn in part to a method of treating a human

subject suffering from cachexia comprising administering a therapeutically effective amount of the humanized PM-1 antibody, said antibody blocking signal transduction from Il-6 by inhibiting the binding of Il-6 to the Il-6 receptor. Emilie et al teach the alleviation of the symptoms of cachexia in human patients by a method comprising the administration of an antagonist to the Il-6 receptor. Emilie et al do not teach the administration of the humanized PM-1 antibody. Sato et al teach the humanized PM-1 antibody, wherein the administration of said antibody is effective in blocking signal transduction by Il-6. It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the humanized PM-1 antibody for the antagonist of the Il-6 receptor used by Emilie et al in the treatment of cachexia. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Sato on the in vitro efficacy of the humanized PM-1 antibody in blocking of Il-6 mediated signal transduction in human cells, and the suggestion by Sato et al that the PM-1 antibody will be a useful therapeutic agent in humans.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
February 12, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER